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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,213	09/16/2003	Hassan Mostafavi	005513P021	3361

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EXAMINER	
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ART UNIT	PAPER NUMBER
3737	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/664,213	MOSTAFAVI ET AL.	
	Examiner	Art Unit	
	Jonathan G. Cwern	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-16,49,51-58,62-79 and 81-89* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-16,49,51-58,62-79 and 81-89* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/7/10 has been entered.

Claim Objections

Claims 83 and 87are objected to because of the following informalities:

Claim 83 appears to be redundant now in view of the amendments to claim 1.

In claim 87, "the high energy treatment beam" lacks antecedent basis.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 5-7, 13-14, 16, 49, 51-58, 62, 76-77, 82-84, and 87-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) in view of Cosman (US 2002/0065461) and Jaffray et al. (US 2003/0007601).

Mate et al. show a guided radiation therapy system. The radiation delivery source can be a linear accelerator, or any other type of radiation therapy device ([0034]). The radiation device has a machine isocenter associated with it. This is the isocenter of the radiation beam ([0035]). A plurality of markers are positioned in the target to mark the actual location of the target in the body. These markers define a target isocenter. The target isocenter is selected as part of a treatment planning procedure by a treatment planning system ([0054]). The position and orientation of each marker is obtained using a radiofrequency signal and used to determine the precise location of the target isocenter ([0036]-[0037]). The markers can be implanted in the patient, and delivered by an applicator needle ([0041]). The actual position of the target isocenter is compared to the position of the machine isocenter, and if they are spatially misaligned, the target can be moved relative to the machine isocenter. Once

the target isocenter and machine isocenter are coincident, the radiation treatment is applied ([0039]). Determining the position manually would be a well known and obvious modification to one of ordinary skill in the art. Mate et al. fail to show using more than one imaging modality.

Cosman discloses a surgical positioning system. Cosman teaches that X-ray imaging can be used to further refine the positioning of the isocenter. The X-ray images can be used to determine the position of markers within the body. The use of X-ray imaging further improves the accuracy of the alignment ([0064]-[0069]). Furthermore, the same imaging modality could be used. Cosman teaches the use of preoperative CT scanning ([0064]) and the use of interoperative CT scanning as well ([0065]). These imaging systems are located on different machines, one being used for planning the treatment and one being used for the actual treatment. As indicated by applicant's specification ([0064]), various configurations are known in the art and may be used, including imagers located on a gantry or as part of a treatment table. Cosman also teaches that both the treatment machine and the patient can be moved to accomplish desired positional relationships ([0024]). The treatment machine is rotatable ([0025]). A multileaf collimator or any other type of known collimator can be used as well ([0026]). The angle and shape of the treatment beam can be controlled ([0043]).

Jaffray et al. disclose a radiation therapy system. Jaffray et al. teach that kV or MV imaging can be used to aid in lesion location ([0008]).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used a second imaging system to align the patient and the

treatment beam as taught by Cosman in the system of Mate et al. The use of a second imaging system will increase the accuracy of the alignment. Furthermore as part of the combination of using a second imaging system to aid in patient alignment as taught by Cosman, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have modified the system of Mate et al. to locate the position of the markers using imaging rather than a radiofrequency signal as taught by Cosman. Mate et al. recognize that there are a variety of known techniques for locating the position of a target within the body which could be employed ([0074[).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the combined device of Mate et al. and Cosman with any imaging modality which will aid in the radiation therapy process, kV or MV imaging being two such possible imaging modalities which are known for aiding in lesion location.

Claims 8-9, 12, 78-79, and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) in view of Cosman (US 2002/0065461) and Jaffray et al. (US 2003/0007601) as applied to claims 6 and 7 above, and further in view of Jang (US 5757953).

Jang discloses an automated method and system of region decomposition in digital radiographic images. Jang teaches that shape filtering and connected component analysis are used to decompose an image into meaningful subregions (column 11, lines 30-67). The median filters can be used to smooth the image (column

9, line 3). The details of the operation of median filtering are old and well-known in the art.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used a median filter and connected component analysis as taught by Jang, in the combined system of Mate et al., Cosman, and Jaffray et al.. One of ordinary skill in the art would have used these techniques to divide the image into useful regions, and to find the location of the markers in the images. In addition, by determining the location of markers in the image, the user would know which objects are not markers. It would be obvious to one of ordinary skill in the art to make sure that these objects would then not be considered as markers, and would not be used for any further steps, such as during the alignment.

Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) in view of Cosman (US 2002/0065461) and Jaffray et al. (US 2003/0007601) and Jang (US 5757953) as applied to claim 8 above, and further in view of Gerig et al. (US 5446548).

Gerig et al. disclose a patient positioning and monitoring system. Gerig et al. teach the use of an epipolar line constraint (column 5, lines 19-43). Such a technique is old and well known in the art.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used an epipolar line constraint technique as taught by Gerig et al. in the combined system of Mate et al., Cosman, Jaffray et al., and Jang.

One of ordinary skill in the art would use such a technique to aid in aligning the markers in the sets of images.

Claims 15, 63-72, and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) in view of Cosman (US 2002/0065461) and Jaffray et al. (US 2003/0007601) as applied to claims 1 and 14 above, and further in view of Fitzpatrick et al. (US 6073044).

Fitzpatrick et al. disclose a method for determining the location in physical space of a point of a fiducial marker. Fitzpatrick et al. teach that a rigid body transform is necessary to register and align the coordinate systems of two imaging modalities (column 1, lines 42-58). A rigid body transform technique is old and well known in the art.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used a rigid body transform technique as taught by Fitzpatrick et al., in the combined system of Mate et al., Cosman, and Jaffray et al. When using two imaging modalities, such a technique will allow for the two imaging spaces to be properly registered and aligned, and thus the markers in the two images to be aligned. This will allow for the proper positioning adjustment to be determined and executed.

Also, it would have been obvious to have used the same angle for image as for a treatment beam, as this will reduce the amount of time between acquiring images and moving the treatment system into the proper location, because it is already in the proper

location. A shorter time between imaging and treatment will prevent more motion from occurring in between, which would reduce the accuracy of the system.

Claims 73 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) in view of Cosman (US 2002/0065461) and Jaffray et al. (US 2003/0007601) and Fitzpatrick et al. (US 6073044) as applied to claim 64 above, and further in view of Carol (US 5622187).

Carol discloses a method and apparatus for patient positioning for radiation therapy. Carol teaches that multiple positioning images can be acquired and a triangulation technique used (column 8, line 61-column 9, line 25).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have acquired images from different angles as taught by Carol in the combined system of Mate et al., Cosman, and Jaffray et al. Acquiring an image from more than one angle provides additional data that can be used for three-dimensional reconstruction. If the images were acquired at the same angle, this would not be possible.

Claims 85-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) in view of Cosman (US 2002/0065461) and Jaffray et al. (US 2003/0007601) as applied to claims 1 and 58 above, and further in view of Ishikawa et al. (US 6398710).

Ishikawa et al. disclose a radiation dosimetry system. Ishikawa et al. teach the use of implantable devices which measure the radiation delivered to the target site (column 4, lines 25-50).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have modified the combined system of Mate et al., Cosman, and Jaffray et al. to measure the radiation dosage at the target site as taught by Ishikawa et al. Such techniques are well known in the art, and are commonly used in radiation treatment systems, as they allow the physician to determine the optimal radiation dose to treat the patient with, without damaging nearby healthy tissue.

Response to Arguments

Applicant's arguments filed 6/7/10 have been fully considered but they are not persuasive.

First, the examiner would like to address a misconception present throughout applicant's arguments. Applicant argues that the Cosman reference relies upon external, camera imaged markers. However, these markers are **not** relied upon by the examiner, as the examiner has made clear in prior arguments. The examiner has cited paragraphs [0064]-[0069] in Cosman. In [0064] Cosman refers to initial scanning by a CT system with fiducial markers. In paragraph [0067] Cosman refers to further refining the internal target position to an isocenter by using X-ray images from an x-ray machine or portal imager (a common device on modern LINACS), to visualize radiopaque markers implanted in tissue. This step does not refer to external, camera imaged

markers, but rather to implanted markers imaged via x-ray. Thus, applicant's arguments in regards to the external, camera imaged markers of Cosman found throughout the bulk of applicant's arguments are moot, as they are not relied upon in the rejection. Furthermore while also moot, applicant states that Mate teaches against using external markers. This is simply false as Mate devotes entire sections of the disclosure to an alternative embodiment which employs surface mounted markers, such as in paragraph [0064].

Next the examiner believes it would be most beneficial to respond to applicant's arguments by describing an overall view of the combination of Mate et al. and Cosman. Mate et al. essentially teaches the main concept of applicant's invention, which is using markers to align a patient for a radiation treatment. Mate et al. however locate the markers by using markers which emit a radiofrequency which can then be detected externally. Applicant's invention on the other hand, uses imaging to locate the markers. However, Mate et al. note in paragraph [0074] that "In general, in the following claims, the terms used should not be construed to limit the invention to the specific embodiments disclosed in the specification and the claims, but should be construed to **include all target locating and monitoring systems that operate in accordance with the claims to provide apparatus and methods for locating, monitoring, and/or tracking the position of a selected target within a body."** Thus, Mate et al. is aware of other apparatus and methods for locating the markers within the body. The examiner thus combines the Cosman reference, which describes a similar patient alignment system but using imaging to locate markers rather than detection of an RF signal. For

these reasons the examiner feels that the combination of the references is appropriate, and would have been obvious to one of ordinary skill in the art at the time the invention was made.

It should also be noted that applicant's claims do not necessarily require that the determination of the coordinates is performed using the images. Thus the markers detected by an RF signal in Mate et al. would be sufficient to meet those limitations of the independent claims. In any case, as described above, it would be obvious to modify Mate et al. in view of Cosman to obtain the location of markers via imaging.

In regards to applicant's arguments regarding kV and MV imaging, this limitation was previously present in claim 4, and was rejected in combination with a third reference Jaffray et al., which teaches a similar radiation therapy system which employs these imaging modalities.

In regards to applicant's arguments regarding the dependent claims, applicant has attacked the references individually, and does not consider the combination of references. The combination of Mate et al. and Cosman would result in Mate et al. using imaging to locate markers rather than an RF signal, and would thus use the location obtained by imaging to perform a variety of other features such as patient alignment or would have present in the system additional imaging systems to perform the imaging.

Furthermore, applicant also states in these sections that "Cosman only teaches that diagnostic X-rays or high energy X-rays can be used to visualize markers prior to treatment (see paragraph 67)." The examiner believes that applicant has misconstrued

what Cosman means. The quote from Cosman paragraph [0067] is "Thus, diagnostic x-rays from machines 80 and 81 or high energy X-rays for portal imaging can be used to visualize internal anatomy such as bones **and/or radiopaque index markers placed on the skin or implanted in bones or tissue within the patient prior to treatment**" (emphasis added). Thus, it can be seen that Cosman refers to the implantation of the markers prior to treatment, not imaging prior to treatment. Indeed, applicant's interpretation would not make sense in the context of the paragraph which refers to further refinement of the target positioning by imaging.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In regards to applicant's arguments regarding the Ishikawa reference, examiner respectfully disagrees. Ishikawa teaches that implanted devices can be used to measure the radiation delivered to a target site. Measuring the radiation at the site is commonly used in radiation treatment systems, as it is imperative for the operator to prevent healthy tissue from being damaged, and to prevent overexposure to the patient. Such a radiation detection system could be combined with the sensors of Mate or Cosman. The examiner disagrees that the systems would interfere with one another. It is well known that such interference can be prevented in a variety of methods, such as using different frequencies, or operating the devices at separate times. For example,

the device of Mate uses multiple markers and can distinguish between them by using frequency multiplexing [0049]. Ishikawa teaches that the frequency of an electromagnetic wave used to power the transponder is different from the frequency used to transmit the data (paragraph bridging columns 9 and 10). One of ordinary skill in the art would not be prevented from combining such references. As illustrated throughout the references, there are a variety of different types of markers, methods for positioning, imaging, etc. that are known in the art and it would be obvious to one of ordinary skill in the art to substitute and combine these different modalities, as they all yield the same end result of aiding in patient positioning for radiation treatment.

As a final matter, applicant makes several other arguments directed at "false markers of claim 12", which is not found in the claim; and the gantries of claim 60, of which the claim has been cancelled.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is (571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan G Cwern/
Examiner, Art Unit 3737

/BRIAN CASLER/
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